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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,914	09/09/2003	Bret A. Ferree	BAF-14802/29	5106

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EXAMINER
PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/657,914	FERREE, BRET A.	
	Examiner	Art Unit	
	Paul B. Prebilic	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 11-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 11-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. On line 1 of claim 20, the term "including" after the preamble is not understood because it is unclear what element(s) has two bioresorbable components.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims set forth the man made device in combination with a part of a naturally occurring living organism. For this reason, the claim language is considered non-statutory. In order to overcome this objection, the examiner suggests changing "attached to a vertebral body" (claim 11, line 2) to --- adapted to be attached to a vertebral body---. Claims 12-20 depend upon claim 11 so they also contain the same non-statutory language.

With regard to claim 19 and 20, these claims use additional non-statutory language that sets forth that the implant is attached to a particular location on the

vertebral body. For this reason, these claims need to be amended in order to overcome the rejection under Section 101.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Cauthen (US 6,019,792). Cauthen anticipates the claim language where the bio-resorbable components are the endcaps (90) of Cauthen, and the artificial disc replacement as claimed is the implant (10); see the abstract and Figure 2. Since the assembled device of Cauthen is capable of being assembled and "located outside an intradiscal space", the claim language is considered fully met in this regard.

With regard to claim 2, the endcap (90) of Figure 2 is considered to be a plate to the extent that this term limits the claim language.

With regard to claims 3-7, the claimed features are considered to be inherent since all solid materials would have these properties to some extent. Additionally, the endcap would inherently limit the degree of motion until it is resorbed.

Claims 11-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Dixon et al (US 6,695,845). Dixon anticipates the claim language where the component as claimed is met by the plate and screw combination of Dixon that can be resorbable and attached to either side of the vertebral space; see the abstract, column 4, lines 15-37, column 5, lines 30-42 and Figure 1.

With regard to claim 18, Applicant is directed to column 8, lines 25-26 of Dixon.

Claims 11-17 and 19-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Trieu et al (US 2002/0120270). Trieu anticipates the claim language where the component(s) as claimed are the implants of Trieu; see paragraphs [0032] to [0037].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen (US 6,019,792) in view of Nicholson et al (US 6,096,080). Cauthen meets the claim language as explained in the Section 102 rejection, but fails to disclose using allograft material; see column 4, lines 60-65. However, Nicholson teaches using materials similar to Cauthen as well as allograft material to make a similar disc implant was known; see column 9, lines 42-52. Therefore, it is the Examiner's position that it would have been obvious to use at least some allograft as the implant material of Cauthen for

the same reasons that Nicholson uses the same; see column 10, line 59 to column 11, line 17 of Nicholson.

It is noted that claimed ADR appears to be inferentially recited, the claim language may not require a teaching of an allograft material for the ADR as claimed. Nonetheless, Nicholson teaches that such devices were known and that the claimed invention is at least obvious.

Response to Arguments

Applicant's arguments filed September 28, 2005 have been fully considered but they are not persuasive. Applicant argues that Cauthen does not anticipate the claim language because it is not intended to be used such that the caps are located outside the intradiscal space. However, since this language is merely a statement of intended use and since the device of Cauthen can be assembled and located outside an intradiscal space, the Examiner asserts that the claim language is fully met.

ABP 12-20-05

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Prebilic
Primary Examiner
Art Unit 3738